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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,923	09/22/2006	Venkatram P Shastri	RCHP-128US	4606

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EXAMINER	
DESAI, ANAND U	
ART UNIT	PAPER NUMBER
1656	
MAIL DATE	DELIVERY MODE
12/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,923	SHASTRI ET AL.	
	Examiner	Art Unit	
	Anand U. Desai, Ph.D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *26-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I, claims 1-25, drawn to a construct comprising a polymeric matrix and a nanoparticle in the reply filed on October 9, 2007 is acknowledged.

2. Claims 26-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 9, 2007.

3. Claims 1-25 are currently under examination.

Priority

4. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(e). The priority date is March 28, 2003.

Specification

5. The disclosure is objected to because of the following informalities:

6. There are typographical errors, on page 4, line 11, the word, "lidand" appears to be "ligand", on page 6, line 25, the word, "call" appears to be "cell", and on page 7, line 20, the phrase, "be then" appears to be "then be".

Appropriate correction is required.

Claim Objections

7. Claim 7 is objected to because of the following informalities:

8. In claim 7 suggest standard Markush language, "...the bioactive polypeptide is a growth factor ~~and such growth factor is a member~~ selected from the group consisting of ....".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. In claim 1 how is a structure in the micron size range a nanoparticle?

12. In claim 1 it is unclear how the nanoparticle comprises a structure? The nanoparticle is a structure. It is unclear if the particle a spherical structure or some other structure?

13. In claim 1 how does the monomolecular layer comprise biological information? Does the monomolecular layer comprise a molecule which inherently possesses a biological function?

14. In claim 2, how is ligand-substrate binding not already claimed by the other types of bonds disclosed? It appears redundant or is otherwise unclear what type of bond is being referred to.

15. In claim 3, how can the outermost monomolecular layer ever be anything but external to an innermost layer?

16. Claims 4-25 are rejected for depending on a rejected claim and failing to cure the indefiniteness of the claims.

Claim Rejections - 35 USC § 112

17. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

18. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original).

Just as the claims at issue in *UC v. Lilly* defined the invention by the function of the claimed DNA (encoding insulin), the instant claims define the claimed products only by their functional properties (e.g. derivatives of chemical functional groups). The court held this sort of functional definition insufficient. "In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as 'vertebrate insulin

cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is." *UC v. Lilly*, at *24-*25, thus the above claims lack adequate written description, because the person having ordinary skill in the art would not distinguish the genus from others. What are the structural modifications for the chemical functional groups that encompass the derivatives thereof?

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

20. Claims 1-6, 8-10, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Simonnet et al. (U.S. Patent 6,379,683 B1).

21. Simonnet et al. disclose a nanocapsule comprising a lipid core forming or containing a lipophilic active principle, and a water-insoluble continuous polymeric envelope, wherein said polymeric envelope comprises at least one dendritic polyester polymer which contains a terminal hydroxyl groups. The nanocapsules are surrounded by a lamellar coat, wherein the coat can be silicone surfactants, which are capable of forming lamellar structures. The nanocapsules have a mean size of between 50 nm and 800 nm. The encapsulated lipophilic active principles can be selected from a group consisting of emollients, anti-inflammatory agents, antibacterial agents, antifungal agents, antiviral agents, and antihistamines, in addition to other compositions (claims 1, 13, 14, 15, and 16).

22. Claims 1, 2, 5, 6, 8-11, 13-20, 22, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Ketelson et al. (U.S. Patent Application Publication 2005/0002970 A1).

23. Ketelson et al. disclose nanoparticles of inorganic materials for use in ophthalmic and otic pharmaceutical compositions. The nanoparticles can contain either silica, aluminum oxide, titanium oxide, and zinc oxide (see claim 8). The composition can be in the form of a solution, a thixotropic gel (see claims 9, and 10). The compositions can also contain one or more polymers, such as carboxy vinyl polymers or galactomannans (see paragraph 42).

24. Claims 1, 2, 5, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Oppenheim et al. (U.S. Patent 4,107,288).

25. Oppenheim et al. disclose injectable nanoparticle compositions. The particles comprise a crosslinked matrix of macromolecules selected from a group that can contain collagen. The

particle comprises a biologically or pharmacodynamically active material supported on or incorporated into the crosslinked matrix (see claims 9-18).

Claim Rejections - 35 USC § 103

26. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

27. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

28. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

29. Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simonnet et al. (U.S. Patent 6,379,683 B1) or Ketelson et al. (U.S. Patent Application Publication 2005/0002970 A1) or Oppenheim et al. (U.S. Patent 4,107,288) in view of either Perez, C. et al. (Journal of Controlled Release) and Li et al. (US 2002/0187104 A1).

30. Simonnet et al. (U.S. Patent 6,379,683 B1), Ketelson et al. (U.S. Patent Application Publication 2005/0002970 A1), and Oppenheim et al. (U.S. Patent 4,107,288) are discussed above in the 35 U.S.C. 102 rejections.

Perez, C. et al. disclose the process of producing a poly(lactic acid)-poly(ethylene glycol) nanoparticle containing a co-encapsulated DNA plasmid-poly(vinyl) alcohol (PVA) or poly(vinylpyrrolidone (PVP). Li et al. disclose a composition and a method of making and a method of using for the delivery of osteogenic protein, a calcium phosphate material as a carrier, and an effective amount of an effervescent agent. The calcium phosphate material can comprise hydroxyapatite, and tricalcium phosphate. The composition can further comprise collagen, polyesters, and silicon oxide (see claims 1-35).

A person having ordinary skill in the art would have encapsulated a biologically active principle as disclosed by Simonnet et al., with the encapsulation method disclosed by Li et al. to enhance the effective delivery. Therefore, it would have been obvious to the person having ordinary skill in the art to manufacture and use a nanoparticle composition to administer to a cell or tissue for repair, regeneration, and augmentation of bone tissue.

Conclusion

31. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

December 24, 2007
AD
/Anand Desai/
Patent Examiner
Art Unit 1656